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108TH CONGRESS
1ST SESSION

H. R. 725

To amend the Federal Food, Drug, and Cosmetic Act to establish labeling and advertising requirements for dietary supplements containing ephedrine alkaloids, to prohibit sales of such supplements to individuals under the age of 18, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 12, 2003

Mrs. DAVIS of California introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish labeling and advertising requirements for dietary supplements containing ephedrine alkaloids, to prohibit sales of such supplements to individuals under the age of 18, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Ephedrine Alkaloid Consumer Protection Act''.

SEC. 2. REQUIREMENTS REGARDING DIETARY SUPPLEMENTS CONTAINING EPHEDRINE ALKALOIDS.

(a) FOOD LABELING AND ADVERTISING.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

''(w) If it is a dietary supplement containing ephedrine alkaloids, unless its labeling and advertising are in accordance with the following, as applicable:

''(1) The label bears, in at least 1/16 inch type, a notice as follows:

'''WARNING: (A) Not for use by individuals under the age of 18. Do not use if pregnant or nursing. Consult a physician or licensed qualified health care professional before using this product if you have, or have a family history of, heart disease, thyroid disease, diabetes, asthma, high blood pressure, recurrent headaches, depression or other psychiatric condition, glaucoma, difficulty in urinating, prostate enlargement, or seizure disorder, or if you are using monoamine oxidase inhibitor (MAOI) or any other dietary supplement, prescription drug, or over-the-counter drug containing ephedrine, pseudoephedrine, caffeine, or phenylpropanolamine (ingredients found in certain al-

lergy, asthma, cough or cold, and weight control products).

"'(B) Consuming this product may cause serious adverse health effects, including heart attack, stroke, and death.

"'(C) Discontinue use and call a physician or licensed qualified health care professional immediately if you experience rapid heartbeat, dizziness, severe headache, shortness of breath, or other similar symptoms.

"'(D) Individuals who consume additional caffeine with this product may experience serious adverse health effects.

"'(E) This product contains ____ milligrams concentrated ephedrine group alkaloids per serving in the form of herbal extracts.'.

In lieu of the blank, the number of milligrams shall be identified.

"(2) The label bears standardized nomenclature for the ephedrine ingredient such that the ephedrine group alkaloid name is used when referring to the active ingredients in place of or in addition to the botanical name of the ephedrine group alkaloid.

"(3) The label bears the amount in milligrams of caffeine alkaloids and other ingredients per serv-

ing that have a known stimulant effect (ex yohimbine).

''(4) The label bears the toll-free telephone number, and the address of the Internet site, maintained by the Secretary for purposes of the medical product reporting program (MedWatch or any successor program).

''(5) The labeling (other than the label), and all prerecorded or scripted radio or television advertising, provide a notice as follows: 'This product contains ephedrine group alkaloids and may cause serious adverse health effects. Read the label and follow directions.' ''.

(b) SALES TO MINORS.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by inserting after section 403C the following section:

''SALE OF DIETARY SUPPLEMENTS CONTAINING EPHEDRINE ALKALOIDS

''SEC. 403D. The sale of a dietary supplement containing ephedrine alkaloids shall be deemed to be an act that results in such supplement being misbranded while held for sale if—

''(1) the sale of the supplement is made to an individual under the age of 18; or

''(2) in the case of a sale at retail, the purchaser has direct access to the supplement at the retail establishment involved, rather than the supplement being held at a portion of the establishment not intended to be accessible to customers of the establishment.''.

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